REMARKS

Reconsideration of this application is respectfully requested.

Upon entry of the foregoing amendment, claims 3-14 are pending in the application. Claim 3 is amended.

Applicants respectfully request entry of the above amendment and submit that the above amendment does not constitute new matter. Claim 3 is amended to use language that is grammatically clearer without chancing the scope of the claim. Support for the amendment to claim 3 can be found in claim 3 as originally filed and throughout the specification.

Applicants respectfully request reconsideration of the rejection of claims 3-14 in view of the following Remarks and the Declaration submitted herewith.

I. 35 U.S.C. § 112, para. 2

The Office Action states that claims 3-14 are rejected under 35 U.S.C. § 112, para. 2, as being indefinite. In particular, the Office Action states that in "[c]laim 3, line 5 the recitation 'manner' is vague and indefinite." (Office Action, page 2.) Claim 3, as amended in the instant response, no longer contains the term "manner." Thus, the rejection of claims 3-14 under § 112, para. 2, has been rendered moot.

II. 35 U.S.C. § 103

The Office Action maintains the rejection of claims 3-14 under 35 U.S.C. § 103(a) as obvious over Park et al., *Homogenous Proximity Tyrosine Kinase Assays*, Anal. Biochem. 269: 94-104 (1999) ("the Park publication") in view of Applicants' prior sale of cross-linked allophycocyanin ("APC") which had not been exposed to strongly chaotropic agents ("Applicants' product").

In establishing prima facie obviousness, it is necessary to show that one of ordinary skill in the art having the reference before him be motivated to make the proposed substitution, combination or other modification. *In re Lintner*, 458 F.2d 1013, 173 U.S.P.Q. 560 (C.C.P.A. 1972).

The Park publication discloses a method for quantitating an analyte by measuring time resolved transfer of fluorescence energy to or from a labeled quantity, including transfer of energy to conventional cross-linked APC. The Office Action takes the position that one of skill in the art would be motivated to substitute Applicants' product for the conventional cross-linked APC used in accordance with the methods disclosed in the Park publication. (*See* Office Action, page 4.) The Office Action states that the reason there exists motivation for substituting Applicants' product for the conventional cross-linked APC used in accordance with the Park publication is that "it appears that both cross-linking agents would perform equally well in Time-Resolved Fluorescence Assays, therefore a skilled artisan would have a reasonable expectation of success in selecting either cross-linking agent for performing the assay." (Office Action, page 4.)

Applicants respectfully assert that the Declaration by Mark Wesley Moss submitted with the instant Response ("The Declaration") demonstrates that a skilled artisan would clearly not have a reasonable expectation of success in substituting Applicants' product for the conventional cross-linked APC used in accordance with the Park publication because: 1) Applicants' product does not produce improved results over conventional cross-linked APC in standard binding assays; and 2) by contrast, Applicants' product *does* indeed show significantly improved results over conventional cross-linked APC in time-resolved fluorescence assays.

The Declaration establishes that Applicants' product does not produce improved results over conventional cross-linked APC in a routine flow cytometric analysis (see paragraphs 12-16 of the Declaration), nor does Applicants product produce improved results over conventional APC in steady-state fluorescence binding assays in microplate format (see paragraphs 17-20 of the Declaration). Accordingly, one of skill in the art would have no expectation of success in choosing Applicants' product to achieve any particular technical benefit in fluorescence assays. Consequently, one of skill in the art would have no motivation to substitute Applicants' product for conventional cross-linked APC in fluorescence assays.

Indeed, based on the lack of any technical benefits conferred by Applicants' product on uses of standard fluorescent binding assays, one of skill in the art would certainly *not* expect that Applicants' product would produce the significantly improved results discovered by the inventors

over conventional cross-linked APC in time-resolved fluorescence assays. Such results include those results detailed in Examples 6 and 8, which, as set forth in the Declaration (paragraphs 21-24), establish that on an equal mass per test basis, Applicants' product produces improved results over conventional cross-linked APC in intensity and signal-to-noise ratios, and can match conventional cross-linked APC even when used at a lower concentration. Thus, prior to the inventors' unexpected discovery, there was no expectation that the Park publication in combination with Applicants' product would provide an improved assay. Consequently, the present invention is not obvious, and Applicants respectfully request that the rejection of claims 3-14 under 35 U.S.C. § 103(a) be withdrawn.

The Office Action further states that

> With regards to the declaration filed 03/03/05, the declaration is not found persuasive because the declaration is directed to the use of cross-linked allophycocyanin (XL-APC) in a non-time-resolved manner and does not disclose that applicant's product was not sold for use in time-resolved assays . . . .

(Office Action, page 6.)

First, Applicants respectfully note that, as discussed above, the Declaration submitted with the instant response includes not only a discussion of the use of cross-linked APC in standard binding assays that are "non-time-resolved," but also a discussion of the use of cross-linked APC in time-resolved fluorescence assays. Specifically, the Declaration establishes how Applicants' product generates improved results over conventional cross-linked APC in time-resolved fluorescence tyrosine kinase assays.

Second, the Declaration establishes that Applicants' product was indeed not offered to be sold more than one year prior to the filing date of the present application for the purpose of using Applicants' product in assays involving time-resolved fluorescence (see paragraph 4 of the Declaration). Rather, the third party to whom Applicants offered to sell Applicant's product did not use Applicants' product more than one year prior to the filing date of the instant application for a use that involved time-resolved fluorescence.

Therefore, in view of the above Remarks, Applicants respectfully request that the Examiner withdraw the rejection of claims 3-10 under 35 U.S.C. § 103(a).

The Office Action states that claims 11-14 are rejected under 35 U.S.C. § 103(a) as obvious over the Park publication in view of Applicants' prior sale of Applicants' product. For the reasons discussed above with respect to the rejection of claims 3-10, Applicants submit that the rejection of claims 11-14, which depend either directly or indirectly from independent claim 3 and hence incorporate all of the limitations of claim 3, should also be withdrawn.

Accordingly, in view of the Remarks set forth above, it is respectfully requested that the Examiner withdraw the rejection of claims 11-14 under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing Remarks and Declaration submitted herewith, Applicants respectfully submit that claims 3-14 of the instant application are in condition for allowance, and such disposition is earnestly solicited. Should the Examiner believe that any patentability issues remain after consideration of this Response, the Examiner is invited to contact the Applicants' undersigned representative to discuss and resolve such issues.

Respectfully submitted,
HUNTON & WILLIAMS LLP

Dated: September 29, 2005 By: _____

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